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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,429	10/20/1999	TOSHIHIRO SHIMIZU	2535USOP	7265

23115 7590 10/09/2002

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EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/403,429	Shimizu et al.
Examiner	**Art Unit**
Susan T. Tran	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 9, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *20, 21, 23-26, 28, and 29* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *20, 21, 23-26, 28, and 29* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time filed 03/14/02, Preliminary Amendment E filed 03/14/02, Amendment F and Translation Paper filed 07/09/02.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20, 21, 23-26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. US 6,299,904.

Shimizu teaches a buccal disintegration formulation comprising low-substituted hydroxypropylcellulose (7.0-9.9 %), sugar, and active agent, such as lansoprazole (columns 1-3). The dissolution time of the buccal formulation is from about 5 to about 50 seconds (column 8, lines 1-5). Although Shimizu teaches lansoprazole among many other active agents may be used, it is the position of the examiner that it would have been obvious for the skilled artisan to, by routine experimentation obtain the claimed invention, because Shimizu specifically teaches the use lansoprazole in example 5. The expected result would be a storage stable of quick dissolved formulation of lansoprazole, which can be orally administered without water.

2. Claims 20, 21, 23-26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al. US 5,958,453, in view of Shimizu et al.

Ohno teaches improved buccal disintegrability formulation comprising active agent, mannitol or erythritol, cellulose, e.g., low-substituted hydroxypropyl cellulose (columns 2-5). The formulation can be compressed into tablet that has dissolution time of about 0.1 to 1.0 minute (column 6, lines 65-67).

Ohno does not expressly teach the claimed active agent, *e.g.*, lansoprazole.

Shimizu teaches a buccal disintegration formulation comprising low-substituted hydroxypropylcellulose (7.0-9.9 %), sugar, and active agent, such as lansoprazole (columns 1-3). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Ohno's formulation using lansoprazole as an active agent in view of the teaching of Shimizu. The reason for this modification is to obtain a buccal disintegrable solid dosage useful for the treatment of the digestive diseases.

Although Ohno is silent as to the teaching of the degree substituted of the hydroxypropyl group, Ohno recognizes the advantages result in obtaining buccal tablet having dissolution time within the claimed range. However, it would have been prima facie obvious for one of ordinary skill in the art to, by routine experimentation select a suitable low-substituted hydroxypropyl cellulose to obtain a rapid disintegrate buccal tablet. The expected result would be a buccal dissolution dosage that has long shelf-life, low toxicity, ease of administration even without water, and having fast disintegration in the oral cavity even without water (column 7, lines 3-25).

3. Claims 20, 21, 23-26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al., and Shashoua et al. US 5,795,909.

Although Ohno teaches variety of active agents useful for the gastrointestinal function, Ohno is silent as to the specific active agent claimed by the applicant, e.g., lansoprazole.

Shashoua teaches pharmaceutical composition in tablet form comprising active ingredients, e.g., lansoprazole (column 35, lines 4-10). The composition further comprising pharmaceutically acceptable carrier (column 48, lines 22-32). Thus, it would have been obvious for one of ordinary skill in the art to modify Ohno's formulation using lansoprazole as an active agent in view of the teaching of Shashoua. The reason for this modification is to obtain a buccal disintegrable solid dosage useful for the treatment of the digestive diseases. The expected result would be a storage stable quick dissolve buccal formulation that can be safely administered orally without water.

Response to Arguments

4. Applicant's arguments filed 07/09/02 have been fully considered but they are not persuasive.

Applicant argues that claims 22 and 27 were not rejected over Ohno et al., and by incorporating the subject matter of claims 22 and 27 into claims 20 and 21, the claimed invention is patentable over the cited reference. However, the reason Ohno was not relied on for the rejection of claims 22 and 27 was stated in the last office action, that was Ohno does not teach

lansoprazole as active ingredient. Ohno is now combined with Shimizu for the specific disclosure of lansoprazole as an antacid agent. Although Ohno does not teach lansoprazole, Ohno discloses at column 3, lines 1-15 that no limitation to the pharmaceutically active ingredients to be used, for example, gastrointestinal function conditioning agents, and antacids. Lansoprazole is well known in pharmaceutical art to be useful for the treatment of digestive function, therefore, it would have been obvious to one of ordinary skill in the art to modify Ohno's gastrointestinal function conditioning agents or antacids using lansoprazole in view of the teaching of Shimizu et al., and Shashoua et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600